July 11, 2002

Natalie Rutherford
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

Dear Ms. Rutherford:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester, posted on the ChemRTK HPV Challenge Program Web site on February 5, 2002. I commend the FMC Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its HPV Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that FMC Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester

SUMMARY OF EPA COMMENTS

The sponsor, FMC Corporation, submitted a test plan and robust summaries to EPA for Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (Methyl DVEster) (CAS #61898-95-1) dated December 28, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 5, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. EPA agrees with the submitter's proposal to conduct partition coefficient and biodegradation tests. All other appropriate SIDS-level tests/estimations have been performed and adequate robust summaries have been submitted.

2. Health Endpoints. EPA reserves judgement on whether Methyl DVEster meets the criteria for a "closed system intermediate," pending the receipt of additional information. Provided adequate documentation is provided, EPA agrees that only a developmental study (deferred until 2003) and an in vitro chromosomal aberration test need to be performed.

3. Ecotoxicity. All appropriate SIDS-level tests have been performed and adequate robust summaries have been submitted. The robust summary for the algal study needs to report the 96-hour value.

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON CYCLOPROPANECARBOXYLIC ACID, 3(2,2-DICHLOROETHENYL)-2,2-DIMETHYL-, METHYL ESTER CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

EPA agrees with the submitter's proposal to conduct a partition coefficient test. Adequate existing data are available for the other endpoints.

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

EPA agrees with the submitter's proposal to conduct a biodegradation test. Adequate existing data are available for the other endpoints. However, the submitter needs to provide the in-put values for the fugacity calculation.

Health Effects

The submitter proposes to conduct a developmental toxicity study (deferred until 2003) and an in vitro chromosomal aberration assay. Adequate data are available for the acute and genetic (bacterial) toxicity endpoints. The submitter notes that neither repeated dose toxicity nor reproductive toxicity data are needed because Methyl DVEster is a "closed system intermediate" as defined by EPA for the HPV Challenge Program.

Reproductive and Repeat Dose Toxicity

The Guidance for Testing Closed System Intermediates for the Challenge Program http://www.epa.gov/chemrtk/guidocs.htm allows for a reduced testing proposal provided certain criteria are met. The information required to judge a "closed system intermediate" claim must address the following:

I. Site information.
    A. Number of sites.
    B. Basis for "closed process" conclusion at each site.
        1) Process description.
        2) Monitoring data showing no detection.
        3) In the absence of monitoring data, the basis for believing that releases do not occur.
    C. Data on "presence in distributed products."
II. Information on transport (mode, volume, controls, etc.)
III. A data search showing that the chemical is not present in other endproducts.

EPA believes that the submitter has generally addressed the criteria described above. However, EPA requests clarification on a number of points. The submitter indicates that Methyl DVEster is used on site to manufacture other substances. However, it is not clear if the monitoring information also pertains to those activities. The submitter indicates that the average concentration in the wastewater stream is 678 ppm. It is not clear from the description if this concentration is in the wastewater stream sent to the on-site carbon bed treatment facility or the wastewater stream sent to the POTW after carbon bed treatment. The submitter supplied a process diagram for the one off-site facility processing the substance operated by Syngenta Crop Protection, Inc. In the test plan the off-site facility is identified as a Zeneca facility. The submitter has confirmed they are one and the same. Consequently, provided the submitter addresses the above points to satisfy the standards for meeting the "closed system intermediate" claim, repeat dose and reproductive toxicity tests do not need to be conducted.

Ecological Effects (fish, daphnid, and algal toxicity).

Adequate existing data are available for these endpoints. However, the robust summary for algae indicates that there are 96-hour data available and these data need to be submitted.

Specific Comment on the Robust Summaries

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

Transport/distribution. The submitter needs to provide the in-put values for the fugacity calculation.

Ecological Effects (fish, daphnid, and algal toxicity).

Algae. In addition to the 120-hour data the 96-hour data should also be reported for comparison purposes with other studies.

Followup Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.